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JTW AF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Kenneth F. Buechler, et al.

Title: METHODS FOR MONITORING THE STATUS OF ASSAYS AND IMMUNOASSAYS

Appl. No.: 09/712,615

Filing Date: 11/13/2000

Examiner: Lisa V. Cook

Art Unit: 1641

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EV 727838874US (Express Mail Label Number) November 17, 2005 (Date of Deposit)

Vanessa E. Agha (Printed Name)

Vanessa E Agha (Signature)

APPEAL BRIEF TRANSMITTAL

Mail Stop Appeal Brief - Patents
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Sir:

Transmitted herewith are the following:

[X] Amended Appeal Brief (20 pages) including Appendix A (6 pages) and Appendix B (1 page).

[X] The fee required for additional claims is calculated below:

	Claims As Amended		Previously Paid For		Extra Claims Present		Rate		Additional Claims Fee
Total Claims:	22 .	-	92	=	0	x	$50.00	=	$0.00
Independent Claims:	2	-	3	=	0	x	$200.00	=	$0.00
First presentation of any Multiple Dependent Claims:						+	$360.00	=	$0.00
CLAIMS FEE TOTAL								=	$0.00

[X] No fee should be done for the Appeal Brief since this was paid for previously on December 19, 2002.

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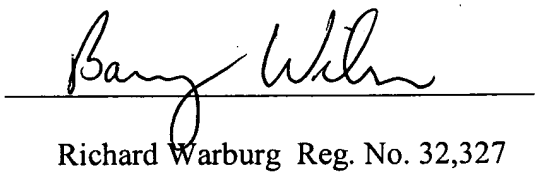
[X] The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17 or § 41.20, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Please direct all correspondence to the undersigned attorney or agent at the address indicated below.

Respectfully submitted,

Date November 17, 2005

By 

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PATENT
071949-4102

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Kenneth F. Buechler et al.

Title: METHOD FOR MONITORING THE STATUS OF ASSAY AND IMMUNOASSAY

Appl. No.: 09/712,615

Filing Date: November 13, 2000

Examiner: Lisa V. Cook

Art Unit: 1641

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EV 727838874US (Express Mail Label Number)
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Vanessa E. Agha (Printed Name)

Vanessa E Agha (Signature)

AMENDED APPEAL BRIEF

Mail Stop Appeal Brief - Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This "Amended Appeal Brief" is responsive to a Notice of Non-Compliant Appeal Brief mailed 10/19/2005. Appellants hereby appeals the Final Rejection of claims 27, 28, and 93-128. Documents listed in Evidence Appendix B have been provided earlier and are not attached. The fee for this Appeal Brief (37 C.F.R. § 41.20(b)(2)) should not be done since it was paid for an earlier Appeal Brief filed December 19, 2002.

Table of Contents

Table of Publications

Real Party in Interest

The real party in interest in this appeal is Biosite Incorporated (formerly Biosite Diagnostics, Inc.), which is the assignee of the present application.

Related Appeals and Interferences

No related appeals or interferences are pending.

Status of Claims

Claims 1-26 and 29-92 have been cancelled.

Claims 27, 28, and 93-128 are pending in the application. For the convenience of the Board, the pending claims are presented in Appendix A of this Brief.

Claims 27, 28, and 93-128 are the subject of this appeal.

Claims 27, 28, and 93-128 stand finally rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

Claims 27, 28, and 93-128 stand finally rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to satisfy the written description requirement.

Claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 stand finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Buechler, U.S. Patent 5,458,852, in view of Van Deusen *et al.*, U.S. Patent 5,132,097.

Claims 95 and 117 stand finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Buechler, U.S. Patent 5,458,852, in view of Van Deusen et al., U.S. Patent 5,132,097, in further view of Slovacek *et al.*, U.S. Patent 5,242,837.

Claims 28, 101, 102, 104, 107, 108, 127, and 128 stand finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Buechler, U.S. Patent 5,458,852, in view of Van Deusen et al., U.S. Patent 5,132,097, in further view of Foster *et al.*, U.S. Patent 4,444,879.

Claim 103 stands finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Buechler, U.S. Patent 5,458,852, in view of Van Deusen et al., U.S. Patent 5,132,097, in further view of Slovacek *et al.*, U.S. Patent 5,242,837, and Foster *et al.*, U.S. Patent 4,444,879.

According to the Examiner, Claims 97, 98, 105, 106, 119, and 120 would be allowable if written in independent form.

Status of Amendments

No amendments are outstanding.

Summary of Claimed Subject Matter

The claimed subject matter relates to assay devices for determining the presence or amount of an analyte of interest in a sample, and kits containing such devices. Analyte assays have become increasingly important in clinical settings. Because such assays must often be performed outside of a well controlled laboratory setting and by non-expert personnel (*e.g.*, in an emergency room setting by emergency medical technicians), the ability to provide simple assay devices that perform in a predictable fashion is at a premium. Specification, page 1, line 21, through page 2, line 17. Prior to the present invention, predictability in such simple devices could be problematic, due to variations in conditions of device manufacture, in the sample matrix, and in environmental conditions under which the device is used. Specification, page 10, lines 6-15.

One issue raised in performing an assay is determining whether a low signal from the analyte in the assay results from: 1) a completed assay where the low signal accurately reflects a low level of analyte in the test sample, or 2) an incomplete assay where the low signal is an underepresentation of the level of analyte in the test sample. Independent claim 27 which has the following elements, addresses this issue.

> 27. (Previously presented) An apparatus for measuring progress and time of completion of an assay for an analyte, comprising:
>
> (a) an assay device comprising:
>
> (i) a reaction chamber comprising an optically detectable label, and
>
> (ii) at least one diagnostic lane comprising at least one assay zone configured to bind said analyte and at least one timing zone separate from the assay zone, wherein said diagnostic lane is in fluid communication with said reaction chamber, and wherein, when

fluid is added to said reaction chamber, said detectable label flows with said fluid to said at least one diagnostic lane to contact said at least one timing zone;

(b) an optical component configured to detect an optical signal generated from said label in said at least one timing zone and generate an electronic signal in response; and

(c) a signal processor configured to receive said electronic signal and to determine said progress and time of completion of said assay for said analyte in said assay device from at least one parameter selected from the group consisting of a rate of change of the amount of said electronic signal and an amount of said electronic signal.

In an effort to address these issues of predictability, the present invention discloses for the first time the use of independent assay controls (IAC's) in assay devices. Specification, page 2, line 20.

With respect to independent claim 27, the specification teaches IACs for measuring progress and time of completion of an assay for an analyte. Specification, page 12, line 30 to page 15, line 6. Such apparatus comprises: (a) the assay device, comprising a reaction chamber and at least one diagnostic lane; (b) an optical component; (c) a signal processor. Specification, page 14, lines 16-25. Also included is a label in the reaction chamber which preferably does not appreciably bind to any assay reagents in the assay device.

The "timing zone" signals of the present claims, provide control signals that do not depend upon assay results for the analyte of interest, but that are dependent upon the non-analyte characteristics of the sample being analyzed and the particular characteristics of the individual assay device being used. *See, e.g.*, specification, page 31, lines 24-29. The IAC results are "independent" of the analyte assay, meaning the signal from the IAC is not a function of the analyte determination. As such, IACs provide a predictable signal that may be used to determine one or more parameters of the assay being performed in the device.

In claim 27, the invention features an apparatus configured for "measuring progress and time of completion of an assay for an analyte of interest," and the IAC used for this purpose is a signal obtained from a "timing zone." As for all IACs described in the specification, the timing zone provides a signal that is "predictable within a range, set by the manufacturer." Specification,

page 31, line 25. This timing function "allows the instrument to judge when the assay process is complete." Specification, page 40, lines 18-19.

In the rejected claims, a "timing zone" is a zone within an assay device that is separate from the assay zone(s) that bind the analyte(s) of interest. The "timing zone" and the "optical component" are interrelated, in that the optical component is "configured to detect" an optical signal generated from label in the timing zone and generate an electronic signal in response. The electronic signal is then used by a "signal processor" that is "configured to receive" the electronic signal and to determine the progress and time of completion of the assay(s) from the signals received. Thus, the signal generated from the timing zone provides a measurement of assay progress and completion that is independent of the assay for the analyte of interest.

Claim 28 is directed to a kit for measuring progress and time of completion of an assay for an analyte, comprising:

(a) at least one set of instructions for measuring said progress and time of completion; and

(b) an apparatus according to claim 27.

The specification at page 14, lines 26 to page 15, line 6 describes various components of the invention kit including a set of instructions.

Grounds for Rejection to be Reviewed on Appeal

1. The rejection of Claims 27, 28, and 93-128 for being indefinite under 35 U.S.C. §112, second paragraph for use of the term "timing zone."

2. The rejection of Claims 27, 28, and 93-128 for failing to comply with the written description requirement of 35 U.S.C. §112, first paragraph for use of the phrase "timing zone separated from the assay zone."

3. The rejection of Claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 as being unpatentable under 35 U.S.C. §103(a) over Buechler, U.S. Patent 5,458,852, in view of Van Deusen *et al.*, U.S. Patent 5,132,097.

4. The rejection of Claims 95 and 117 as being unpatentable under 35 U.S.C. §103(a) over Buechler, in view of Van Deusen et al., in further view of Slovacek *et al.*, U.S. Patent 5,242,837.

5. The rejection of Claims 28, 101, 102, 104, 107, 108, 127, and 128 as being unpatentable under 35 U.S.C. §103(a) over Buechler, in view of Van Deusen et al., in further view of Foster *et al.*, U.S. Patent 4,444,879.

6. The rejection of Claim 103 as being unpatentable under 35 U.S.C. §103(a) over Buechler, in view of Van Deusen et al., in further view of Slovacek *et al.* and Foster *et al.*, U.S. Patent 4,444,879.

Argument

1. Rejection of Claims 27, 28, and 93-128 under 35 U.S.C. §112, second paragraph (definiteness)

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of indefiniteness for the term "timing zone" under 35 U.S.C. §112, second paragraph. In the rejection, the Examiner first isolates the term "timing zone" from any context provided by both the specification and the claims themselves, setting up an analysis that is devoid of any meaningful definiteness inquiry, which requires that one interpret the claims as a whole and in the light of the specification. After divorcing the term "timing zone" from all context, the Examiner then alleges that the term "timing zone" is somehow a "relative term," and that it is unclear how the various elements of the claim relate to one another. However, when the claims are properly analyzed, the definiteness standard is met. Accordingly, Appellants respectfully request that the rejection of Claims 27, 28, and 93-128 be withdrawn or reversed.

When determining definiteness, the proper standard to be applied is "whether one skilled in the art would understand the bounds of the claim when read in the light of the specification." *Credle v. Bond*, 25 F.3d 1566, 1576, 30 USPQ2d 1911, 1919 (Fed. Cir. 1994). Recognizing that the English language is not always precise, the settled law has established that the essential inquiry in a definiteness analysis is whether the claims set out and circumscribe the claimed subject matter with reasonable particularity. *See, e.g.*, MPEP § 2173.02; *see also, Miles Laboratories, Inc. v. Shandon, Inc.*, 997 F.2d 870, 875, 27 USPQ2d 1123, 1127 (Fed. Cir. 1993)

("If the claims read in the light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more.") (emphasis added). Definiteness is not analyzed in a vacuum, but in light of the content of the specification, and with the knowledge available to the skilled artisan.

As discussed above, the present claims refer to devices for measuring the presence or amount of at least one analyte. The "timing zone" referred to in the instant claims is one embodiment of an "independent assay control" (IAC). As described in the specification, IACs are control measurements that provide a signal that is generated in connection with, but that is independent of, the signal obtained from the assay for the analyte of interest.

As described in the instant specification, *e.g.*, beginning on page 73, section entitled "*Use of the Timing Signal to Detect Assay Completion of Immunoassay Devices*," the phrase "timing zone" refers to a zone within an assay device where a signal is detected for use in determining if the assay for the analyte of interest has run to completion. Methods and devices for determining the progress and time of completion of assays using a signal obtained from such a "timing zone" are described in detail in the instant specification, *e.g.*, on page 13, line 7, through page 14, line 15; page 40, line 9, through page 42, line 23; page 70, line 15, through page 71, line 11; and page 73, line 6, through page 75, line 30.

In full agreement with the specification's discussion of what is meant by a "timing zone," the rejected claims describe an apparatus for measuring progress and time of completion of an assay for an analyte comprising the following elements (from Claim 27):

(i) an assay device comprising

a reaction chamber comprising an optically detectable label; and

at least one diagnostic lane comprising at least one assay zone configured to bind the analyte of interest, and at least one timing zone separate from the assay zone;

(ii) an optical component configured to detect an optical signal generated from the timing zone and generate an electronic signal in response; and

(iii) a signal processor configured to receive said electronic signal and to determine said progress and time of completion of said assay for said analyte in

said assay device from at least one parameter selected from the group consisting of a rate of change of the amount of said electronic signal and an amount of said electronic signal.

Thus, according to the literal language of the rejected claims, (i) a timing zone is a zone within an assay device that is separate from the assay zone(s) that bind the analyte(s) of interest; and (ii) from the timing zone, a signal is generated from a label within the assay device, the signal is then used by a signal processor to determine the progress and time of completion of the assay(s) for the analyte(s) of interest. Considering the literal language of the claims, and the extensive teachings in the instant specification concerning the design and use of timing zones, Appellants respectfully submit that the skilled artisan is reasonably apprised of the scope of the claims with regard to the "timing zone" recited in the claims. As noted above, it is well settled that 35 U.S.C. § 112, second paragraph, demands no more.

Despite this clear description of the claimed subject matter, the Examiner asserts that the phrase "timing zone" should be considered a "relative term." *See,* Office Action mailed May 5, 2005, page 3. The reasoning given for this is that "[t]here is no requirement for an assay zone and a separate 'timing zone' or a 'timing zone' monitoring a measurable signal that is independent of the analyte." *Id.*, page 4. Since that is precisely what the claims literally recite (i.e., ". . . timing zone separate from the assay zone . . ."), the Examiner's rationale for the conclusion cannot be understood. The Examiner's conclusion is also at odds with the specification which, for example, describes measuring signals from "detection zones" (page 70, line 28), and determining a signal from a "timing zone" that is separate from any of these detection zones (page 71, lines 3-4). In short, the Examiner has provided no meaningful explanation for why the term "timing zone" is "relative," and what it might be relative to. It is respectfully submitted that the Examiner's remarks, which interpret the term "timing zone" unfettered by any context, are at odds with the requirement that the claims be interpreted in the light of the specification and by viewing the claim as a whole. *See, e.g.*, MPEP § 2173.02.

The Examiner further argues that the rejected claims are indefinite "because the interaction of the timing zone is unclear" (sic). Office Action mailed May 5, 2005, page 3. Specifically, the Examiner appears to believe that the timing zone must be located downstream

from the assay zone(s), and that the timing zone must somehow bind to a label. *Id.* Appellants respectfully submit that this is simply incorrect.

No particular relationship between the assay zone(s) and the timing zone is required, either by the claims or by the specification. For example, the skilled artisan would understand that the timing zone may be placed at the distal end of the diagnostic lane (described as a preferred embodiment of the invention; *See, e.g.*, specification, page 41, lines 11-15). But the timing zone might also be placed parallel to the assay zone, or may even precede the assay zone. If made necessary by positioning of the timing zone in the device, the criteria for a measurement at the timing zone that defines assay completion may be derived empirically. *See, e.g.*, specification, page 41, lines 22-23. Why such breadth should somehow render the claim indefinite is unclear.

Likewise, the Examiner's assertion that "the label does not clearly bind to either of the zones to produce a detectable product" (Office Action mailed May 5, 2005, page 3) is not relevant to the definiteness of the claims, and fails to consider the extensive teachings of the specification on the subject. Neither the claims nor the specification require that the label used to generate a signal at the timing zone be bound to the timing zone at the time. For example, while binding of the label to the timing zone is one embodiment of the present invention, a signal may also be generated from label flowing *through* the timing zone. *See, e.g.*, specification, page 71, lines 4-6.

Finally, Appellants note that the rejection is inconsistent with the Examiner's statement that Claims 97 and 98 are allowable if written in independent form. These claims, which depend from independent Claim 27, only further limit Claim 27 by reciting that the label used at the timing zone binds to the timing zone. These claims do not cure any deficiencies alleged by the Examiner except the final assertion that "the label does not clearly bind to either of the zones to produce a detectable product." The fact that the Examiner believes that such claims should be allowable only serves to underscore the fact that the rejection is not founded upon the proper standard by which definiteness is judged.

Appellants respectfully submit that, in a proper analysis, the phrase "timing zone" should not be interpreted in a vacuum as the Examiner has apparently done, but rather in light of the

extensive teachings in the instant specification and from the point of view of one possessing the ordinary level of skill in the art. The clear interrelation of the optical component and the signal processor with the timing zone in the claims, together with the teachings of the specification, provide the necessary context to reasonably understand the scope of the claims. In contrast, the Examiner has failed to perform the required definiteness analysis in a meaningful fashion. Because the definiteness requirement of 35 U.S.C. § 112, second paragraph, has been met, Appellants respectfully request that the rejection of Claims 27, 28, and 93-128 be withdrawn or reversed.

2. Rejection of Claims 27, 28, and 93-128 under 35 U.S.C. §112, first paragraph (written description)

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of a lack of written description under 35 U.S.C. §112, first paragraph. The rejection is predicated on a bare allegation that the specification "does not show support" for "an apparatus having at least one timing zone separated from the assay zone." Office Action mailed May 5, 2005, page 4. Because, as discussed above, the Examiner is clearly incorrect in this allegation, Appellants respectfully request that the rejection of Claims 27, 28, and 93-128 be withdrawn or reversed

The proper standard for determining compliance with the written description requirement of 35 U.S.C. § 112, first paragraph, is whether the specification reasonably conveys to the skilled artisan that the inventor was in possession of the claimed invention as of the filing date. *See* MPEP § 2163.02 (citing *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 227 USPQ 177, 179 (Fed. Cir. 1985)). The subject matter of the claimed invention need not be described literally in the specification in order to satisfy the requirements of 35 U.S.C. § 112, first paragraph. *Id.* In a careful analysis of the written description requirement provided by Patent and Trademark Office in its *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 ¶1, "Written Description" Requirement*, it is stated that an adequate written description "may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention." 66 Fed. Reg. 1099, 1105 (2001) (emphasis added).

In describing the claimed invention, the specification states that the progress and time of completion of an assay, a timing zone signal is measured at "a discrete zone" in the diagnostic lane. *See, e.g.*, specification, page 13, lines 11-15; page 41, lines 6-10; and page 42, lines 2-4. The specification also states that the assay measurement may be made in one zone, and the IAC signal (*e.g.*, the timing zone signal) measured in another zone. *See, e.g.*, specification, page 12, line 30, through page 13, line 21. The specification also provides an example where the timing zone is "downstream of the last detection zone"; thus, in this example, the timing zone is separate from the assay zone. *See, e.g.*, specification, page 71, lines 2-4.

In the face of this seemingly clear and unmistakable support for "an apparatus having at least one timing zone separated from the assay zone," the Examiner provides the following analysis of whether the claims meet the written description standard: "The disclosure does not show support form (sic) this limitation." Office Action mailed May 5, 2005, page 4. The Examiner points to page 73, lines 13-25 of the specification, alleging that this particular section of the specification "appears to teach a 'timing signal zone' or 'timing zone' along the entire diagnostic lane wherein a signal is measured every ten seconds by window advancement over the discrete zones of the device." Office Action mailed May 5, 2005, page 5. But whether or not the Examiner is correct (and nothing in the cited section indicates that timing zones and assay zones are not distinct locations), the cited section does not negate those portions of the specification that provide explicit support for the claims as written. The Examiner's failure to consider the specification as a whole, or explain why the specification fails to reasonably convey to the skilled artisan that the inventor was in possession of the claimed invention, renders the rejection fatally flawed.

Moreover, Appellants note that the rejection is inconsistent with the Examiner's statement that Claims 97 and 98 are allowable if written in independent form. As discussed above, these claims only further limit independent Claim 27 by reciting that the label used at the timing zone bind to the timing zone. These claims should not have been allowable if the Examiner's rationale for the written description rejection were sound. Nevertheless, the Examiner believes that such claims should be allowable.

In view of the clear teachings in the instant specification, Appellants respectfully submit that the skilled artisan is reasonably informed that Appellants were in possession of "an apparatus having at least one timing zone separated from the assay zone," the only written description basis on which the Examiner objects to the claims. Because the written description requirement of 35 U.S.C. § 112, first paragraph, has been met in this regard, Appellants respectfully request that the rejection of Claims 27, 28, and 93-128 be withdrawn or reversed.

3. Rejection of Claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 under 35 U.S.C. §103(a)

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103 for the rejection of Claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 over Buechler, U.S. Patent 5,458,852, in view of Van Deusen *et al.*, U.S. Patent 5,132,097. The publications cited in the rejection, considered alone or together, do not teach or suggest each and every element of the present claims. Additionally, because the Examiner has failed to consider various claim elements in the rejection, there is no motivation established by the Examiner to modify the cited publications to provide each of the elements of the present claims. Appellants therefore respectfully request that the rejection of Claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 be withdrawn or reversed.

To establish a *prima facie* case of obviousness, three criteria must be met; there must be some motivation or suggestion, either in the cited publications or in knowledge available to one skilled in the art, to modify or combine the cited publications; there must be a reasonable expectation of success in combining the publications to achieve the claimed invention; and the publications must teach or suggest all of the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP § 2142. In analyzing obviousness, the Court of Appeals for the Federal Circuit has repeatedly cautioned that:

> [t]he factual inquiry... must be based upon objective evidence of record.... [T]he best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.... [P]articular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.

In re Sang-Su Lee, 277 F.3d 1338, 1343 (Fed. Cir. 2002) (internal citations omitted).

The claimed apparatus for measuring the progress and time of completion of an assay for an analyte comprise, *inter alia*, the following elements (from Claim 27):

(i) an assay device comprising

a reaction chamber comprising an optically detectable label; and

at least one diagnostic lane comprising at least one assay zone configured to bind the analyte of interest, and at least one timing zone separate from the assay zone;

(ii) an optical component configured to detect an optical signal generated from the timing zone and generate an electronic signal in response; and

(iii) a signal processor configured to receive said electronic signal and to determine said progress and time of completion of said assay for said analyte in said assay device from at least one parameter selected from the group consisting of a rate of change of the amount of said electronic signal and an amount of said electronic signal.

The Examiner begins the obviousness analysis with a flawed perspective of the primary Buechler '852 patent, stating that this patent discloses "a time gate for measuring the reaction in a given period of time." Office Action mailed May 5, 2005, page 7 (emphasis added). A definition of a "time gate" in the '852 patent readily contradicts the Examiner's assertion.

Time Gate

> Referring to FIG. 1a, the time gate 5 holds the reaction mixture in the reaction chamber 4 for a given period of time. The concept of the time gate is that a predominantly aqueous solution cannot pass through a hydrophobic zone until the hydrophobic zone is made hydrophilic. Furthermore, the hydrophobic zone is made hydrophilic by a component in the aqueous solution.

'852 patent, Column 7, lines 41-47 (emphasis added). As is made clear by this definition, the "time gate" of the '852 patent is not involved in *measuring* any reaction, contrary to the Examiner's position; rather, it is a device to *delay* flow across a hydrophobic zone until that zone is made hydrophilic. There is no signal generated from this "time gate;" as such, there is no

progress of an assay and its time of completion determined from a signal from the "time gate." Also, there is no processor configured to receive and process such a signal.

The Examiner also errs in ignoring the "configured to" language of the present claims with respect to question of whether the '852 patent teaches two additional elements of the present claims – the "optical component configured to detect an optical signal generated from the timing zone and generate an electronic signal in response" and the "signal processor configured to read the electronic signal and determine the progress of the assay and its time of completion." By simply ignoring the "configured to" language of the claims, the Examiner concludes that an optical component and signal processor of the '852 patent may be reduced to any and all optical components, and any and all processors, no matter what purpose each serves and how they are configured in a device. *See, e.g.*, Office Action mailed May 5, 2005, page 13 ("the features upon which applicant relies (i.e., structural elements reading on 'configured to') are not recited in the rejected claim(s)").

Appellants respectfully submit that the Examiner is incorrect that the "configured to" language in the present claims is mere surplussage that may be ignored in rejecting the claims. Instead, the recitation of elements "configured to" one another is common in patents and represents a structural limitation that must be considered. *See, e.g.*, *Ex parte Boudry et al.*, Appeal No. 2000-1978, 2001 WL 1176515 at *3 ("As set forth previously, the limitation that the adhesive be configured to contact the wearer's body in use... is a structural limitation"); see also, *Ex parte Yagihashi and Sato*, Appeal No. 2004-2289, 2005 WL 1181897 at *3 (reversing a rejection under 35 U.S.C. §103 of a claim reciting "a purchaser terminal configured to enable a user to view..."), *Ex parte Rosenhain*, Appeal No. 97-0672, 1997 WL 1909599 at *2 (reversing a rejection under 35 U.S.C. §103 of a claim reciting "at least one gripping member configured to engage and removably hold a utensil"); the latter two decisions, while not binding precedent, are cited here as persuasive authority (copies attached in Appendix B).

Appellants reiterate that the '852 patent does not disclose or suggest any optical component configured to detect an optical signal generated from its "time gate" and generate an electronic signal in response, since the '852 patent does not consider the "time gate" to be an element from which a signal either can or should be determined. Furthermore, because there is

no signal to be generated from this "time gate," no processor is configured to determine the progress of an assay and its time of completion from a signal from the "time gate." In short, there is no correspondence between the "time gate" of the '852 patent and the "timing zone" of the present claims and, consequently, the optical component and processor of the '852 patent are not appropriately configured.

The Examiner continues the rejection by further mischaracterizing the teachings of the '852 patent. For example, the Examiner states that "the rate of change is monitored by the flow of reagents through the porous member." Office Action mailed May 5, 2005, page 7. The Examiner refers to column 18, lines 2-8 of the '852 patent to support this assertion. However, the passage does not support the Examiner's conclusion. In fact, it states something completely different -- that fluid control means like a "time gate" can be used to *control* the rate of flow, not to *monitor* the rate of flow, as the Examiner apparently believes.

Then, referring to possible modifications of devices disclosed in the '852 patent, the Examiner states that "the label (signal development element) does not appreciably bind to any reagent in the assay device but could be designed to indirectly cause a visually or instrumentally detectable signal as a result of the assay process." Office Action mailed May 5, 2005, page 7 (emphasis added). Appellants respectfully submit that the mere fact that the devices of the primary '852 patent *could be designed* to meet some limitation of the present claims does not establish that such devices meet the requirements of the instant claims, or provide a motivation to modify the devices of the cited publication. To establish a motivation to modify the prior art, the Examiner must provide some motivation or suggestion, either in the cited references or in knowledge available to the ordinarily skilled artisan to do so (*see, e.g.*, MPEP §2143), rather than simply stating that such a modification *could be* made.

Furthermore, the Examiner's reliance on the secondary Van deusen *et al.* '097 patent solely for the alleged disclosure of "an optical signal detector and signal processor" (Paper No. 24, page 12) fails to fill the gaps from the initial reference. Simply combining these publications to place an optical signal detector and signal processor in a device with a "time gate" as defined in the '852 patent fails to disclose all of the limitations of the instant claims. There is no teaching cited to configure the optical signal detector and signal processor in the manner

claimed. No motivation has been established to do so, since the Examiner apparently believes the requirement for configuration required by the claims can be ignored.

The publications of record, whether considered separately or together, do not disclose or suggest that any signal should be obtained from a discrete timing zone or that a signal processor should be used to determine the progress and time of completion of an assay from that signal. Furthermore, the fundamental elements of an obviousness rejection -- a teaching or suggestion of each element of the claims and a motivation to modify the cited publications to provide the invention as claimed -- are lacking from the Examiner's asserted *prima facie* case.

Because the publications cited in the rejection, considered alone or together, do not teach or suggest each and every element of the present claims, and because no motivation has been established to modify the cited publications to provide each of the elements of the present claims, Appellants respectfully submit that no *prima facie* case of obviousness has been established. Accordingly, Appellants request that the rejection of Claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 under 35 U.S.C. § 103(a) be withdrawn or reversed.

4. Rejection of Claims 95 and 117 under 35 U.S.C. §103(a)

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103 for the rejection of Claims 95 and 117 over the Buechler '852 patent, in view of the Van Deusen *et al.* the '097 patent, and a new secondary reference -- Slovacek *et al.*, U.S. Patent 5,242,837.

Because the new secondary publication is cited only for the disclosure of "a fluorometer as a useful optical detector" (Office Action mailed May 5, 2005, page 8), the fatal flaws in the Examiner's rejection based on the '852 and '097 patents remain fatal flaws in this rejection. Specifically, the rejection is flawed because (i) it is founded upon multiple mischaracterizations of the teachings of the '852 patent; (ii) the Examiner has disregarded elements of the claims which recite how elements are "coupled to" one another; and (iii) it relies on the assertion that devices in the '852 patent "could be designed" to practice the claimed invention.

The publications cited in the rejection, considered alone or together, do not teach or suggest each and every element of the present claims. Additionally, because the Examiner

ignores various claim elements in the rejection, there is no motivation established to modify the cited publications to provide each of the elements of the present claims. Appellants therefore respectfully request that the rejection of Claims 95 and 117 be withdrawn or reversed.

5. Rejection of Claims 28, 101, 102, 104, 107, 108, 127, and 128 under 35 U.S.C. §103(a)

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103 for the rejection of Claims 28, 101, 102, 104, 107, 108, 127, and 128 over the Buechler '852 patent, in view of the Van Deusen *et al.* '097 patent and another new secondary publication -- Foster *et al.*, U.S. Patent 4,444,879.

Because the new secondary publication is cited only for the disclosure of assays in kit form (Office Action mailed May 5, 2005, page 9), the fatal flaws in the Examiner's rejection based on the '852 and '097 patents remain fatal flaws in this rejection. Specifically, the rejection is flawed because (i) it is founded upon multiple mischaracterizations of the teachings of the '852 patent; (ii) the Examiner has disregarded elements of the claims which recite how elements are "coupled to" one another; and (iii) it relies on the assertion that devices in the '852 patent "could be designed" to practice the claimed invention.

The publications cited in the rejection, considered alone or together, do not teach or suggest each and every element of the present claims. Additionally, because the Examiner ignores various claim elements in the rejection, there is no motivation established to modify the cited publications to provide each of the elements of the present claims. Appellants therefore respectfully request that the rejection of Claims 28, 101, 102, 104, 107, 108, 127, and 128 be withdrawn or reversed.

6. Rejection of Claim 103 under 35 U.S.C. §103(a)

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103 for the rejection of Claims 28, 101, 102, 104, 107, 108, 127, and 128 over the Buechler '852 patent, in view of the Van Deusen *et al.* '097 patent, the Slovacek *et al.* '837 patent, and the Foster *et al.* '879 patent.

This last rejection simply combines the alleged disclosure of "a fluorometer as a useful optical detector" from the '837 patent and the alleged disclosure of assays in kit form from the

'879 patent, with the flawed rejection based on the '852 and '097 patents. Again, those flaws remain fatal flaws in this rejection. Specifically, the rejection is flawed because (i) it is founded upon multiple mischaracterizations of the teachings of the '852 patent; (ii) the Examiner has disregarded elements of the claims which recite how elements are "coupled to" one another; and (iii) it relies on the assertion that devices in the '852 patent "could be designed" to practice the claimed invention.

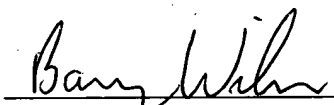
The publications cited in the rejection, considered alone or together, do not teach or suggest each and every element of the present claims. Additionally, because the Examiner ignores various claim elements in the rejection, there is no motivation established to modify the cited publications to provide each of the elements of the present claims. Appellants therefore respectfully request that the rejection of Claim 103 be withdrawn or reversed.

Conclusion

For the reasons discussed above, Appellants respectfully submit that Claims 27, 28, and 93-128 are in condition for allowance, and respectfully request that the rejections be withdrawn or reversed, and that the claims be allowed to issue.

Respectfully submitted,

Date: November 17, 2005

By: 
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Appendix A: Text of the Claims Involved in the Appeal

Claims 1-26 (Cancelled)

27. (Previously presented) An apparatus for measuring progress and time of completion of an assay for an analyte, comprising:

(a) an assay device comprising:

(i) a reaction chamber comprising an optically detectable label, and

(ii) at least one diagnostic lane comprising at least one assay zone configured to bind said analyte and at least one timing zone separate from the assay zone, wherein said diagnostic lane is in fluid communication with said reaction chamber, and wherein, when fluid is added to said reaction chamber, said detectable label flows with said fluid to said at least one diagnostic lane to contact said at least one timing zone;

(b) an optical component configured to detect an optical signal generated from said label in said at least one timing zone and generate an electronic signal in response; and

(c) a signal processor configured to receive said electronic signal and to determine said progress and time of completion of said assay for said analyte in said assay device from at least one parameter selected from the group consisting of a rate of change of the amount of said electronic signal and an amount of said electronic signal.

28. (Previously presented) A kit for measuring progress and time of completion of an assay for an analyte, comprising:

(a) at least one set of instructions for measuring said progress and time of completion; and

(b) an apparatus according to claim 27.

Claims 29-92 (Cancelled)

93. (Previously presented) The apparatus of claim 27, wherein said label is selected from the group of molecules consisting of dye, fluorescence emitting dye, chemiluminescence emitting

dye, infrared emitting dye, colloidal sol, molecule that generates an electrical signal, molecule that generates a magnetic signal, molecule that generates and electrical and magnetic signal, and enzyme.

94. (Previously presented) The apparatus of claim 27, wherein the assay device is an immunoassay device.

95. (Previously presented) The apparatus of claim 27, wherein the optical component is a fluorometer.

96. (Previously presented) The apparatus of claim 27, wherein the reaction chamber and said at least one diagnostic lane are each within a capillary space.

97. (Previously presented) The apparatus of claim 27, wherein the label is attached to a first member of a binding pair that binds to a second member of the binding pair that is bound to said at least one timing zone of said at least one diagnostic lane.

98. (Previously presented) The apparatus of claim 97, wherein one or both of said first and second members of the binding pair is an antibody.

99. (Previously presented) The apparatus of claim 27, wherein said signal processor determines the progress and time of completion of said assay in said device from the rate of change of the amount of signal.

100. (Previously presented) The apparatus of claim 27, wherein said signal processor determines the progress and time of completion of said assay in said device from the absolute amount of signal.

101. (Previously presented) The kit of claim 28, wherein said label is selected from the group of molecules consisting of dye, fluorescence emitting dye, chemiluminescence emitting dye, infrared emitting dye, colloidal sol, molecule that generates an electrical signal, molecule that generates a magnetic signal, molecule that generates and electrical and magnetic signal, and enzyme.

102. (Previously presented) The kit of claim 28, wherein the assay device is an immunoassay device.

103. (Previously presented) The kit of claim 28, wherein the optical component is a fluorometer.

104. (Previously presented) The kit of claim 28, wherein the reaction chamber and diagnostic lane are each within a capillary space.

105. (Previously presented) The kit of claim 28, wherein the label is attached to a first member of a binding pair that binds to a second member of the binding pair that is bound to said at least one timing zone of said at least one diagnostic lane.

106. (Previously presented) The kit of claim 105, wherein one or both of said first and second members of the binding pair is an antibody.

107. (Previously presented) The kit of claim 28, wherein said signal processor determines the progress and time of completion of said assay in said device from the rate of change of the amount of signal.

108. (Previously presented) The kit of claim 28, wherein said signal processor determines the progress and time of completion of said assay in said device from the absolute amount of signal.

109. (Previously presented) The apparatus of claim 27, wherein said at least one assay zone and said at least one timing zone are located in the same diagnostic lane.

110. (Previously presented) The apparatus of claim 27, wherein said at least one assay zone and said at least one timing zone are located in a separate diagnostic lane.

111. (Previously presented) The apparatus of claim 27, wherein a surface of said at least one timing zone is configured to bind said detectable label.

112. (Previously presented) The apparatus of claim 27, wherein said at least one assay zone does not appreciably bind said detectable label.

113. (Previously presented) An apparatus for measuring progress and time of completion of an assay for an analyte, comprising:

(a) an assay device comprising:

(i) a reaction chamber, and

(ii) at least one diagnostic lane comprising at least one assay zone configured to bind said analyte and at least one timing zone separate from the assay zone, wherein said diagnostic lane is in fluid communication with said reaction chamber, and wherein, when fluid and a detectable label are added to said reaction chamber, said detectable label flows with said fluid to said at least one diagnostic lane to contact said at least one timing zone;

(b) an optical component configured to detect an optical signal generated from said label in said at least one timing zone and generate an electronic signal in response; and

(c) a signal processor configured to receive said electronic signal and to determine said progress and time of completion of said assay for said analyte in said assay device from at least one parameter selected from the group consisting of a rate of change of the amount of said electronic signal and an amount of said electronic signal.

114. (Previously presented) The apparatus of claim 113, wherein said apparatus further comprises said detectable label.

115. (Previously presented) The apparatus of claim 114, wherein said label is selected from the group of molecules consisting of dye, fluorescence emitting dye, chemiluminescence emitting dye, infrared emitting dye, colloidal sol, molecule that generates an electrical signal, molecule that generates a magnetic signal, molecule that generates and electrical and magnetic signal, and enzyme.

116. (Previously presented) The apparatus of claim 113, wherein the assay device is an immunoassay device.

117. (Previously presented) The apparatus of claim 113, wherein the optical component is a fluorometer.

118. (Previously presented) The apparatus of claim 113, wherein the reaction chamber and said at least one diagnostic lane are each within a capillary space.

119. (Previously presented) The apparatus of claim 113, wherein the label is attached to a first member of a binding pair that binds to a second member of the binding pair that is bound to said at least one timing zone of said at least one diagnostic lane.

120. (Previously presented) The apparatus of claim 119, wherein one or both of said first and second members of the binding pair is an antibody.

121. (Previously presented) The apparatus of claim 113, wherein said signal processor determines the progress and time of completion of said assay in said device from the rate of change of the amount of signal.

122. (Previously presented) The apparatus of claim 113, wherein said signal processor determines the progress and time of completion of said assay in said device from the absolute amount of signal.

123. (Previously presented) The apparatus of claim 113, wherein said at least one assay zone and said at least one timing zone are located in the same diagnostic lane.

124. (Previously presented) The apparatus of claim 113, wherein said at least one assay zone and said at least one timing zone are located in a separate diagnostic lane.

125. (Previously presented) The apparatus of claim 113, wherein a surface of said at least one timing zone is configured to bind said detectable label.

126. (Previously presented) The apparatus of claim 113, wherein said at least one assay zone does not appreciably bind said detectable label.

127. (Previously presented) A kit for measuring progress and time of completion of an assay for an analyte, comprising:

(a) at least one set of instructions for measuring said progress and time of completion; and

(b) an apparatus according to claim 113.

128. (Previously presented) A kit for measuring progress and time of completion of an assay for an analyte, comprising:

(a) at least one set of instructions for measuring said progress and time of completion; and

(b) an apparatus according to claim 114.

Appendix B: Evidence Appendix

1. Buechler, U.S. Patent 5,458,852, cited by the Examiner in Office Action mailed August 24, 2001

2. Van Deusen *et al.*, U.S. Patent 5,132,097, cited by the Examiner in Office Action mailed August 24, 2001

3. Slovacek *et al.*, U.S. Patent 5,242,837, cited by the Examiner in Office Action mailed August 24, 2001

4. Foster *et al.*, U.S. Patent 4,444,879, cited by the Examiner in Office Action mailed November 24, 2003

5. *Ex parte Boudry et al.*, Appeal No. 2000-1978, 2001 WL 1176515

6. *Ex parte Yagihashi and Sato*, Appeal No. 2004-2289, 2005 WL 1181897

7. *Ex parte Rosenhain*, Appeal No. 97-0672, 1997 WL 1909599